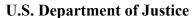
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United States Attorney Southern District of New York

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September 3, 2021

VIA ECF & E-MAIL

Hon. J. Paul Oetken United States Courthouse 40 Foley Square New York, New York 10007

Re: United States v. Scott Mangini, 20 Cr. 162 (JPO)

Dear Judge Oetken:

Scott Mangini ("Mangini" or the "defendant"), for almost a decade leading up to his arrest, was at the helm of a scheme to profit from the creation, marketing, sale, and distribution of illegal adulterated and misbranded drugs across the country, including performance-enhancing drugs ("PEDs") marketed to racehorse trainers, veterinarians, and others. These drugs were not manufactured in sanitary, government-approved facilities; they had not been tested and approved for use in humans or animals by the Food and Drug Administration ("FDA"); they were not distributed pursuant to lawful prescriptions¹; nor were they properly labeled with, among other things, manufacturer information, directions for use, ingredients, or other details designed to ensure that users can mitigate adverse reactions to particular drugs,² and that a contaminated or

¹ Mangini claims in his letter to the Court that the adulterated and misbranded omeprazole paste he developed, Ulcerguard, did not require a prescription. (*See* Mangini Ltr. at 1). In fact, and as Mangini states in his sentencing submission, if he were a legitimate a compounding pharmacy distributing an unapproved drug "he *did* need to maintain proper prescriptions" which he categorically did not do for Ulcerguard. Def. Mem. at 3. Given Mangini's disregard for Florida Department of Health regulations, it is unsurprising that he would contradict himself in this manner. Clearly, in inaccurately describing this drug as an over the counter or "OTC," Mangini seeks to minimize his actions. Moreover, at the time, Mangini clearly knew that he was required to maintain prescriptions for another adulterated and misbranded drug containing omeprazole, UlcerRx, for which Mangini generated false prescriptions using the veterinary license of codefendant Dr. Michael Posner. In any event, Mangini's claim suggests that an unsanitary OTC drug is somehow less problematic simply because it was purportedly available "over the counter" as an OTC through other, FDA-approved, sanitary manufacturers. The claim is baseless and reflects Mangini's continuing failure to acknowledge the scope of his criminal activity.

² For example, the ingredients of a particular drug are relevant for human or animal patients with allergies, a history of negative reactions to a particular substance, or are receiving other

harmful batch of drugs can be traced back to its production facility and recalled before similarly-contaminated drugs cause illness or injury in other users.

Mangini, who held various pharmaceutical licenses throughout the course of the scheme and was consequently well aware of both state and federal regulations regarding the manufacture and distribution of drugs, nonetheless supplied co-conspirators, like convicted co-defendant Scott Robinson, with custom-made drugs that Mangini had manufactured for resale. These drugs by their marketing, design, and effect were specifically targeted at those in the racehorse industry seeking to boost the performance of their racehorses so the horses could be compelled to race beyond their natural ability. After years of supplying Robinson with drugs to be sold over the Internet on various direct-to-consumer websites, Mangini and others took over and operated their own website to sell Mangini-manufactured drugs to those in the racehorse industry. The website url, www.racehorsemeds.com, dispels any ambiguity as to the customers Mangini solicited or the industry to which he catered. Mangini sold a multitude of drugs, including injectable drugs and drugs advertised as those that would enhance a horse's race performance, to laypeople, despite the risks of harm to the receiving animals from being administered drugs: (1) by people without the requisite medical training; and, in many cases, (2) those whose incentives were not to ensure the health of the receiving animal, but to increase the animal's speed and mask their pain so the animal could continue racing despite natural, physical limitations. Many of these drugs, despite being advertised as having a performance-enhancing effect on racehorses, were promoted as of the type that "will not test" even if the directions for use directed administration of the drug within hours of a race, in violation of the racing rules in many jurisdictions.

They were able to offer discounted prices on certain "knock-off" products that purported to offer the same effects as FDA-approved counterpart drugs precisely because they did not engage in the rigorous drug approval and registration process required under the Food Drug and Cosmetic Act ("FDCA") – processes designed to ensure the health of humans and animals receiving drugs. Mangini's businesses made millions of dollars in revenue by disregarding these regulations and continuing to distribute adulterated and misbranded drugs with impunity.

Mangini's conduct is particularly pernicious for two reasons. First, Mangini operated under the auspices of a legitimate pharmacy and took steps to "paper over" his illegal conduct (such as, for example, generating false prescription records to conceal his illegal sale of prescription drugs, when no valid prescription existed) in order to deflect attention from his illegal manufacture and dispensation of large quantities of drugs. Second, Mangini operated with total impunity, giving no regard whatsoever to customer complaints when horses became ill, concerns raised by his own co-defendant, Robinson, regarding his unsanitary practices, or intervention by the Florida Department of Health, who suspended then reinstated and restricted Mangini's pharmaceutical license after discovering numerous, serious violations with Mangini's operation of his pharmacy.

medications that may cause an unexpected side effect when interacting with the drugs sold by Robinson.

For the reasons explained herein, the Guidelines sentence of 60 months' imprisonment is appropriate to address the nature of the offense, the recalcitrant character of this defendant, and to provide adequate deterrence and continued protection for the welfare of the public.

I. Procedural History

On March 9, 2020, Mangini was arrested on the charges in Indictment 20 Cr. 162, namely, two counts of participating in conspiracies related to his distribution in interstate commerce of adulterated and misbranded drugs with the intent to defraud and mislead, in violation of Title 18, United States Code, Section 371. The charges were based on Mangini supplying custom-made drugs to resellers (such as Robinson) and, later, to customers directly through several businesses and websites dedicated to the marketing and sale of performance-enhancing drugs to members of the public, particularly those in the racehorse industry.

As set forth in the Indictment and the Presentence Investigation Report prepared by the United States Probation Department (the "PSR"), Mangini, often obscuring his involvement by hiding behind other people, entities, and false addresses, manufactured and sold a wide variety of drugs, including blood builders, used to increase red blood cell counts and/or oxygenation to stimulate a horse's race performance and recovery; analgesics, designed to block pain, which can mask physical injuries; and red acid, similarly used to reduce inflammation in joints and reduce pain. PSR ¶ 13. He did so by partnering with various co-conspirators, among them each of his three co-defendants. Although the contours of the conspiracy changed over time (employing different shell companies, websites, and participants), the core of the conspiracy remained the same: to manufacture (often in unsanitary facilities) and distribute adulterated and misbranded drugs on the mass market, knowing that such conduct was illegal and wrong.

On April 23, 2021, mere weeks away from trial and only after a substantial preview of the Government's case at trial, Mangini pled guilty pursuant to a plea agreement to a Superseding Information charging Mangini with participating in a single, encompassing count of participating in a drug adulteration and misbranding conspiracy, in violation of Title 18, United States Code, Section 371.

II. The Presentence Report

The PSR calculates the defendant's adjusted offense level as 29. PSR ¶ 47. The PSR, consistent with the plea agreement, finds that Mangini's Sentencing Guidelines range is 87 to 108 months' imprisonment; however, because the statutorily-authorized maximum sentence is 60 months, the defendant's Guidelines range correspondingly lowers to 60 months' imprisonment, pursuant to U.S.S.G. § 5G1.1. See PSR Sentencing Recommendation Page 25. The Probation Office recommends a sentence of 20 months' imprisonment, based in part on the need to avoid sentencing disparities between co-defendants, and in light of the fact that Scott Robinson was sentenced to 18 months' imprisonment. See PSR Sentencing Recommendation at 26.

Mangini lodged three principal objections to the PSR. See PSR Pages 23-24. First, Mangini objects to the use of the term "performance-enhancing drug" or "PED" preferring the term "animal drug." *Id.* at 23. While "animal drug" is not inaccurate, and encompasses a larger swathe of drugs,

to the extent Mangini seeks to deny that he distributed PEDs, this objection is meritless. The webpages advertising many of the drugs Mangini designed and sold were obviously intended to have performance-enhancing effect based on their names and/or descriptions. Those included: "Blood Building Explosion," "Green Speed," "Growth Factor 5000," "Pre-Race Explosion," "Horse Power!," "Equine Growth Hormone," and various blood builders. Moreover, Mangini's drugs were hawked using assurances to dishonest trainers that his concoctions "WILL NOT TEST." See Exhibit 2 (webpages of products advertised on www.horseprerace.com); Exhibit 3 (webpages of products advertised on www.racehorsemeds.com, including those advertised as increasing performance). Second, Mangini objected that his pharmacy license was not suspended as a result of the Florida Department of Health's inspection of his facility. Id. Yet this license suspension (and later restriction) is documented by the Florida Department of Health online; moreover, Mangini stated in his letter-submission to the Court that he "lost" his pharmacy license "by breaking [his] pharmacy oath," contradicting the gravamen of his objection. (See Mangini Ltr. at 5). Finally, Mangini objected to the offense level enhancement based on his use of sophisticated means on the basis that he did not "manufacture PEDs and did not engage in chemical engineering to avoid detection." Id. at 24. This claim, like others, is readily contradicted by the advertisements for his drugs. Irrespective of Mangini's objection, Mangini agreed as part of his plea agreement that the enhancement applies to the calculations of his offense level under the Sentencing Guidelines and cannot now repudiate that agreement.

III. <u>Defendant Submission</u>

In his effort to convince the Court that a non-custodial six-month term of home incarceration is appropriate, Mangini utterly fails to grapple with the scope of his conduct and its potential harm. See Mangini Sentencing Subm. ("Def. Mem.") at 1. Mangini's minimization of his conduct and his self-serving recitations throughout his sentencing submission that the drugs he sold were safe are contradicted by evidence the Government produced in discovery and highlighted in prior court filings, and which are discussed in more detail in this submission. Mangini seeks to dismiss the risks of unintentionally introducing contaminants into a drug as the result of operating an unregistered manufacturing facility that does not conform to good manufacturing practices. Mangini's repeated claims throughout his submission that he sold no performance-enhancing drugs ("PEDs") is, likewise, easily rebutted by the actual evidence in this case, and his continued refusal to contend with the basic facts of his offense speaks poorly of this defendant's character and to the continued danger posed by a man who refuses to acknowledge the core of his wrongdoing.

Mangini's submission presents a skewed representation of his offense conduct as involving variations of omeprazole paste, and little else. Not so. Mangini created, manufactured, and distributed a multitude of products, many of which were advertised as PEDs, including drugs advertised as blood builders with effects similar to erythropoietin. *Compare* Def. Mem. at 3 (claiming that Mangini did not sell "erythropoietin or other commonly abused substances,"), *with* Exhibit 3 (Racehorsemeds website page listing for sale the drug "Blood Building Explosion" described as "an erythropoiesis-stimulating agent"). Mangini's rosy view of his culpability (and the perceived unfairness of this prosecution and the forfeiture amount to which he agreed as part

of his plea agreement) permeates the entirety of Mangini's submission. Only a few points merit response.

First, Mangini claims at multiple points that the drugs he distributed "were exactly what they were represented to be and were not dangerous." Def. Mem. at 2; id. at 3 ("The products he made were safe. They contained the active ingredients that were promised and advertised."); id. at 4 ("All of these drugs are safe"); id. at 8 ("There are very few criminal cases involving misbranded drugs that are safe and effective, like omeprazole"); id. at 9 ("The [] products sold by Mr. Mangini were [] safe and appropriate."). In many cases, it was impossible to tell what ingredients comprised the drugs Mangini and his co-conspirators advertised, because they were advertised only as containing a "proprietary formula" which could comprise anything. See Exhibit 2 (Blast Off Red Injection contains "proprietary formula"; Numb It Injection (same); Numb It Purple Pain Injection (same); Plug It Bleeder Injection (same); Exhibit 3 (Yellow Explosion advertised as a "proprietary pre-race formula"; Green Speed advertised as "a proprietary formula"); Exhibit 14 (in response to question regarding "the composition of" Blast Off Breather Injection, a response email was sent: "Tell the customer it's a proprietary formula that will not test"). Nor is it correct for Mangini to make the sweeping assertion that his drugs were safe. Even if Mangini were correct that the drugs he distributed contained innocuous ingredients disclosed to the purchaser (and he is demonstrably wrong on that point), his view on the safety of his products does not account for contaminants introduced in an unhygienic, unvetted manufacturing process.³ His views are also contradicted by text messages between Mangini and Robinson that describe numerous issues with the drugs Mangini and Robinson distributed, including horses that became sick as a result of being administered those drugs. See infra Part IV.b. The Government highlighted these very text messages at Robinson's sentencing, and in its motions in limine in advance of trial. And further, as a legal matter, and in light of the risks of unapproved drugs flooding the markets, any unapproved drug is considered "unsafe" under the Food Drug and Cosmetic Act. And absent any studies indicating that the drugs did what they were supposed to do, Mangini cannot say that his products were "effective." Def. Mem. at 8.

Second, Mangini asserts that he never manufactured and sold PEDs, insisting repeatedly that his business focused on omeprazole paste. See, e.g., Def. Mem. at 4-5; id. at 8 ("There are very few criminal cases involving misbranded drugs that are safe and effective, like omeprazole"); id. at 9 (Mangini "was selling an ulcer medication"). First, and for the reasons discussed herein, it is false to claim that this case centers on Mangini's distribution of omeprazole—though of course his distribution of that drug was illegal. Mangini persisted in selling a multitude of products, over a long period of time, and his submission does not so much as attempt to explain why the websites advertising his products included descriptions consistent with those for PEDs. The drug "White Lightning" advertised on www.racehorsemeds.com was described as a product that would "increase stamina and performance in racehorses, greyhounds, and camels." Exhibit 3. It was also advertised as of the type that "WILL NOT TEST" and was instructed to be administered "4-6 hours prior to event." Id. Another drug marketed on

³ Mangini's claim that his products were categorically safe and appropriate also conflicts with the facts, detailed below, that he was dismissive when insects and mold, among other contaminants large enough to be observable with the naked eye, were discovered in his products.

www.racehorsemeds.com called "Pre-Race Explosion" was described on the website as "an all in one pre-race formula *designed to increase performance* in horses, dogs, and camels." *Id.* This drug, too, was listed as a drug that "WILL NOT TEST." *Id.* Another product, "Ice Explosion," was similarly advertised as a drug that "works to improve *both sprint and endurance performance* and reduce the perception of pain," and a drug that "WILL NOT TEST." *Id.* Another drug, called simply "Horse Power!" was advertised as "an all in one pre-race formula designed to *increase performance in race horses*, dogs, and camels." *Id.* And contrary to Mangini's assertions that the majority of his sales were omeprazole variants, Ice Explosion was described on the website as "one of our top selling products." *Id.* ⁴

Mangini's offense was long-running. The website with which Mangini was previously affiliated, www.horseprerace.com, sold similar drugs advertised as PEDs. Some of the products Mangini manufactured and offered for sale on www.horseprerace.com included: "Blast Off Red Injection," advertised as a "an extremely potent blood builder injection" that "WILL NOT TEST," Exhibit 2⁵; "Blast Off Extreme Injection," another drug advertised to "increase the force of heart muscle contraction, thereby increasing blood flow and oxygen to the muscles in Race Horses, Greyhound, Dogs, and Camels," *id.*; "Numb It Injection," another injectable drug advertised as the "most powerful pain shot on the market today AND WILL NOT TEST" even if administered "as close to the event as possible, but no closer than 1.5 hrs," *id*; "Red Tide Blood Builder Injection," described as "[t]he most potent blood builder we carry for a one time use," and – in an explicit nod to those seeking to circumvent racing rules and regulations – an assurance that the product "will not test or swab," *id*. These drugs are merely a selection of the myriad products offered for sale on the websites where Mangini and his co-conspirators distributed adulterated and misbranded drugs.

In his submission, Mangini points to the volume of sales of drugs containing omeprazole and other so-called therapeutic products. Def. Mem. at 4-5.⁶ That the sales of certain of Mangini's illegal products may have been outpaced by sales of other illegal products is beside

⁴ Indeed, the product pages on www.horseprerace.com contained side panels on the right side of the screen listing the website's "bestsellers," among them, "Numb It Injection" and "Blast Off Extreme Injection" – again, contrary to Mangini's instant assertions.

⁵ This drug, like many others advertised online by Robinson and his co-conspirators, was recommended for use in dogs (on average, greyhounds can weigh between approximately 60-88 lbs.) as well as horses (on average, horses can weigh between approximately 700-1,200 lbs.), even though there was only a single dosage requirement recommendation (5-10 mls). The imprecision as to the directions for use is just one way in which a layperson may have improperly administered this drug and caused grave harm to the receiving animal.

⁶ One of the products on that list, clenbuterol, *is* in fact restricted by racing authorities in various jurisdictions because it can have performance-enhancing effect. *See, e.g.*, Association of Racing Commissioners International Controlled Therapeutic Medication Schedule for Horses – Version 4.0, April 20, 2017, *available at* http://arci.blob.core.windows.net/webdocs/2017_04_CTS_V4_0.pdf (last visited August 31, 2021). The ARCI Model Rules have been incorporated by reference into various jurisdictions' medication rules governing horseracing.

the point: he and/or his co-conspirators *offered* for sale a multitude of drugs advertised as PEDs (and as mentioned above, included some of those drugs among their "top sellers").

Third, Mangini argues for a sentence of home confinement by claiming that this prosecution has unfairly ratcheted up charges against Mangini, whereas in the ordinary course, individuals engaged in distributing adulterated and misbranded drugs would merely face an administrative action by the Food and Drug Administration ("FDA"). Significantly, Mangini does not even attempt to address the many opportunities he was provided in the course of his conspiracy to desist his criminal conduct, including when he or his co-conspirators received FDA warning letters stating that particular drugs were adulterated or misbranded, and when his pharmaceutical license was suspended and then restricted following an inspection by the Florida Department of Health ("DOH"), due to the egregiousness of his violations. Mangini ignored each of these warnings (among others); he cannot now complain that this prosecution "unfairly" targeted him. Mangini points to FDA guidance, dated September 19, 2011, regarding the FDA's enforcement priorities, as apparent proof that the FDA does not take seriously Mangini's conduct. See Def. Mem. at 8 & Def. Mem. Exhibit C ("2011 Guidance"). What Mangini does not highlight for the Court, is that this guidance was intended to apply to "drug products that are being commercially used or sold as of September 19, 2011." 2011 Guidance at 4. The 2011 Guidance specifically stated that "[a]ll unapproved drugs introduced onto the market after that date are subject to immediate enforcement action at any time, without prior notice and without regard to the enforcement priorities set forth," in the 2011 Guidance and that in light of the promulgation of the 2011 Guidance, the FDA "believe[d] it is inappropriate to exercise enforcement discretion with respect to unapproved drugs that a company . . . begins marketing after September 19, 2011." Id. (emphasis added). In short, at best, the 2011 Guidance has no application whatsoever to the vast majority of drugs distributed as part of Mangini's conspiracy, and, in fact, points out that it would be "inappropriate to exercise enforcement discretion" with respect to Mangini and his co-conspirators. Id. Mangini is also incorrect to suggest that a Guidelines sentence would be anomalous. In *United States v. Landers*, the defendant pleaded guilty in connection with distributing a single adulterated and misbranded drug, Super Fecta, in violation of 21 U.S.C. §§ 331, 333, and was subsequently sentenced to the statutory maximum sentence of three years' imprisonment. See Exhibit 4. Mangini's conduct is far more egregious, and criminal consequences are particularly appropriate for a defendant whose disregard for regulatory attempts at intervention is well documented.

Fourth, Mangini's insistence that the Government's superseding indictment was based "on details it heard from Mr. Mangini in . . . interviews," and that the information he provided in proffer sessions "were important to the Government" is flatly incorrect. See Def. Mem. at 1, 7. In point of fact, during those proffers—and as indicated by the fact that Mangini was not signed up as a cooperator—Mangini minimized his conduct and was not forthcoming in many respects. Mangini's submission overinflates the importance of these proffers, particularly regarding the decision to supersede. The Government was equipped with the information to return the superseding indictment well before Mangini's proffer, and was likewise aware of the availability of the legal theory underpinning the now-operative Superseding Indictment. As the Government has previously explained to Mangini, through counsel, and as alluded to at a prior conference, see April 26, 2021 Tr. at 5:16-17:25, the return of the instant superseding indictment was not precipitated by Mangini's proffers almost a year prior, but an attempt to broaden the language in

the charging instrument with respect to the drugs distributed, given Mangini's staunch refusal to acknowledge that he marketed and distributed PEDs and the risk of jury confusion in the face of Mangini's persistent dissembling. Mangini is wrong to suggest that his two proffer sessions with the Government illuminated evidence or a legal theory to the Government that was not previously known. He deserves no credit for this, particularly considering his litigation of this case until less than three weeks before trial.

Fifth, Mangini's arguments that he is less culpable than Scott Robinson, who was sentenced by this Court to 18 months' imprisonment, is also contrary to the evidence and the Government's view. Mangini, unlike Robinson, was a licensed pharmacist who had greater training, expertise, and knowledge—in other words, there is no doubt that Mangini understood at all times that his actions were wrongful and further understood that they represented a betrayal of the trust placed in him as the result of that very position. Further, as a result of Mangini's licensure and operation of a compounding pharmacy, he was able to run his illegal manufacturing operation in plain sight, under a veneer of legitimacy, managing to mislead Florida DOH inspectors through (among other things) false prescription records, and continue his operations. Mangini's separate abdication of the public's trust by abusing his license exacerbates his conduct, and separates him from Robinson.

Mangini's attempts to argue that he was just a "bit" player in Robinson's overarching conspiracy, Def. Mem. at 2, is perplexing, given (1) the proof that Mangini supplied others, and ultimately struck out on his own, without Robinson, and sold drugs through www.racehorsemeds.com; and (2) that Mangini has already agreed in his plea agreement that he operated as a leader and organizer of his criminal scheme. Moreover, Mangini—unlike Robinson—did not "prompt[ly]" plead guilty, as he now bizarrely claims to have done. Def. Mem. at. 7. Robinson entered into a plea agreement and pled guilty on September 16, 2020, six months after he was indicted. Mangini, by contrast, waited until the brink of trial—after having litigated a motion for a bill of particulars, a motion to suppress, and motions *in limine*—to plead guilty.

IV. Sentencing Factors

a. Applicable Law

Although *United States v. Booker* held that the Guidelines are no longer mandatory, it also held that they remain in place and that district courts must "consult" the Guidelines and "take them into account" when sentencing. 543 U.S. 220, 264 (2005). As the Supreme Court stated, "a district court should begin all sentencing proceedings by correctly calculating the applicable Guidelines range," which "should be the starting point and the initial benchmark." *Gall v. United States*, 552 U.S. 38, 49 (2007).

After that calculation, a sentencing judge must consider seven factors outlined in Title 18, United States Code, Section 3553(a): (1) "the nature and circumstances of the offense and the history and characteristics of the defendant;" (2) the four legitimate purposes of sentencing, as set forth below; (3) "the kinds of sentences available;" (4) the Guidelines range itself; (5) any relevant policy statement by the Sentencing Commission; (6) "the need to avoid unwarranted sentence

disparities among defendants;" and (7) "the need to provide restitution to any victims." 18 U.S.C. § 3553(a)(1)-(7); see also Gall, 552 U.S. at 50 & n.6.

In determining the appropriate sentence, the statute directs judges to "impose a sentence sufficient, but not greater than necessary, to comply with the purposes" of sentencing, which are:

- (A) to reflect the seriousness of the offense, to promote respect for the law, and to provide just punishment for the offense;
- (B) to afford adequate deterrence to criminal conduct;
- (C) to protect the public from further crimes of the defendant; and
- (D) to provide the defendant with needed educational or vocational training, medical care, or other correctional treatment in the most effective manner.

18 U.S.C. § 3553(a)(2).

b. Discussion

The 18 U.S.C. § 3553(a) factors particularly applicable here include the need for the sentence to reflect the nature and seriousness of the offense, to promote respect for the law, to provide just punishment for the offense, and to afford adequate deterrence to criminal conduct to the defendant and those similarly situated. See 18 U.S.C. § 3553(a)(2). For the reasons discussed below, the Government believes that a Guidelines sentence of 60 months' imprisonment is appropriate here. A Guidelines sentence is needed to reflect the seriousness of the offense, to promote respect for the law, and to provide just punishment, for the following reasons. See 18 U.S.C. § 3553(a)(2)(A).

First, a significant sentence is warranted given the defendant's attempts to evade detection and thwart law enforcement and regulatory oversight of his criminal operation. Mangini and his co-conspirators employed a myriad of methods to conceal their criminality from law enforcement and to evade customers who may complain about Mangini's drugs and seek to report him to regulators. Among other methods, and at various points throughout the conspiracy, Mangini adopted the following practices: (1) generating false veterinary prescriptions, going so far as to submit those false prescriptions to Department of Health inspectors that were conducting an inspection of his facility in Florida; (2) labeling outgoing shipments to customers of www.racehorsemeds.com with return addresses for mailboxes opened in Person-1's name, located outside of Florida (where Mangini and his co-conspirators manufactured and shipped the drugs they sold)⁷; (3) utilizing a 1099 contractor who worked for the company to set up a shipping company and handle outgoing shipments for www.racehorsemeds.com customer orders, so that anyone tracing the shipping labels would be directed to the contractor, who was not listed as an employee of Mangini's company; (4) utilizing a corporation under Person-1's name in order to present—as deemed necessary—Person-1 and/or his corporation as the operator of

⁷ The practice of falsely labeling outgoing shipments with misleading return addresses was entirely Mangini's. *See* Exhibit 6A. In an October 9, 2014 text message exchange between Robinson and Mangini, Mangini advised Robinson "to change address for shipping" for purposes of "security . . . specially if someone watching that address." *Id.*

www.racehorsemeds.com; (5) advertising products online using language fa these were dietalsely suggesting that these were dietary supplements, not drugs (*i.e.*, a "supplemental source of Vitamins & Amino Acids," "not intended to diagnose, treat, cure or prevent any disease," and no label indicating the product required a prescription), despite the fact that the actual bottles sold were labeled "prescription animal remedy" and the drugs were injectable, not oral⁸; (5) misrepresenting the location of the conspirators' operations on the company's website; (6) listing on tax returns that the corporate entity behind www.racehorsemeds.com distributed "oral animal supplements," and not the injectable prescription drugs that Mangini actually sold; and (7) omitting from the labels of products sold on www.racehorsemeds.com any address or other contact information for a facility or office so customers could not trace the product back to Mangini.

Mangini further sought to mislead or defraud state racing commissions and racetracks through the distribution of drugs marketed as performance-enhancers that would not test positive on drug screens, even if administered intravenously within hours of a race, which were clearly designed with an intent to circumvent prohibitions against "race-day medications," common to many racing jurisdictions. *See* Exhibits 2, 3 (various drugs advertised as of the type that "WILL NOT TEST" despite being blood builders, or those administered within hours of a race, in violation of many jurisdictions' racing rules). As discussed above, Mangini's insistence in his sentencing submission that he and his co-conspirators sold no PEDs rings hollow. This misguided argument does not warrant leniency; if anything, it further underscores why a significant sentence is necessary to promote just punishment, as Mangini has refused to recognize his conduct as wrong, even if he begrudgingly admits that it is illegal.

The defendant's numerous efforts to obscure his conduct are significant because they indicate that the defendant knew precisely that his conduct was illicit, and took extensive and varied measures to make his crime difficult to detect. Indeed, the defendant's actions worked. Several parties were, in fact, misled as a result of the defendant's efforts.

For example, a newspaper article discussing www. racehorsemeds.com listed Person-1 as the domain owner of that website; as a result, a Google search of the words "Racehorsemeds" and "owner" yields the name of Person-1, and not Mangini, who was a 50% stakeholder in the company behind the website, along with convicted co-defendant Carl Garofalo. PSR ¶¶ 76-77. By way of further example, when companies sought to sue Racehorsemeds for patent infringement on the basis that patented products were sold and/or advertised on www.racehorsemeds.com, the suing companies could not determine the individual or company behind the website. See Exhibit 7 at Page 2 ¶ 8 (Complaint alleging the company has locations in Canada and Nebraska); see generally Exhibit 8 (motion to file by alternate means). Significantly, customers were successfully misled. In early 2020, after a customer ("Person-2") had administered omeprazole paste (designed to treat

⁸ Compare Exhibit 5A (www.racehorsemeds.com webpages for Ice Explosion and White Lightning, with no mention of a prescription requirement), with Exhibit 5B (photographs of bottles of these drugs indicating that they required a prescription).

⁹ See Exhibit 16 (www.racehorsemeds.com contact page indicating a location in Richmond, British Columbia, Canada).

¹⁰ See Exhibits 10 (news article), 11 (Google search).

ulcers) purchased from www.racehorsemeds.com to her horse, Person-2's horse became incredibly sick. Person-2 observed a serious deterioration in her horse's health, who became emaciated, suffered poor health for months, and ultimately had to be hospitalized, with veterinarians unable to determine the cause of the horse's rapid decline in health. In Person-2's efforts to treat her horse, she attempted to locate the operator of www.racehorsemeds.com to determine whether there were any contaminants in the paste she had received that had caused her horse's illness. As evidenced by Person-2's report to the FDA, Person-2 believed—consistent with Mangini's intentions—that Person-1 operated www.racehorsemeds.com. *See* Exhibit 9 at 1 (Victim report to FDA). In short, and due to Mangini's and others' efforts to obscure their involvement, various people and entities over time could only link one person to www.racehorsemeds.com: Person-1.

Second, a significant period of incarceration is required in light of the number of times Mangini ignored direct warnings regarding the risks, consequences – and illegality – of his criminal activities.

In 2014, Mangini or his co-conspirators received numerous letters from the FDA naming certain products as being improperly distributed, with citations to various provisions of law. Exhibit 15. This should have left no doubt in Mangini's mind as to whether or not his conduct was permissible. In fact, Mangini and Robinson even discussed the implications of distributing a "legal" drug, *i.e.*, one with FDA approval, with Mangini discouraging Robinson from pursuing efforts to legally distribute the products they were already marketing and selling. Exhibit 6J.

Between 2014 and the first half of 2015, Mangini's business partner and co-conspirator, Robinson, raised numerous concerns with Mangini regarding the quality of products Mangini was supplying. In a text message exchange dated on or about August 21, 2014, Robinson informed Mangini that bottles of "Vitamin c is exploding," to which Mangini responded dismissively, "That's common on all of them." Exhibit 6B. On or about March 30, 2015, Robinson informed Mangini that an employee "has been complaining of bugs coming out of boxes u send. I told him he was crazy until I found one floating in bottle today when labeling. Better check everything because you might have fruit fly or Nat [sic] problem down there. There shouldn't be a way a bug can get into a crimped bottle." Exhibit 6C. On or about April 20, 2015, Robinson alerted Mangini that he had received "a bad photo of pentosan," a product they offered for sale, with "shit floating in it" and "mold inside," which Mangini brushed off, stating, "Just replace- could be anything," and blamed the customer or other variables as the cause. Exhibit 6D. This complaint was reiterated by Robinson in an April 24, 2015 text message in which he stated: "Better check ur filters and rom. We have stuff floating in flunixin." Exhibit 6E. In another text message on or about May 5, 2015, Robinson asked Mangini: "R u making stuff different? I have a lot of stuff that doesn't look same and has stuff floating in it. Blood building peptide has black particles." Exhibit 6F.

These customer complaints came on the heels of an inspection by the Florida Department of Health ("DOH") conducted in December 2015, in which a withering report detailed the extent of the problems with Mangini's practices. Exhibit 12. Mangini's license was immediately suspended, and subsequently reinstated with significant restrictions. The report cited multiple serious deficiencies in Mangini's practices. *See id.* For example, the DOH found that, "[i]n order to maintain sanitary conditions of pharmacy equipment and personnel an adequate sink in

workable condition with running water . . . must be available"; Mangini's company, Ergogenic Labs, in lieu of an operational sink, had only "a ten gallon bucket of water to use for hand washing." Id. at 2-3. The DOH further found "numerous unsanitary conditions," including "open and unlabeled active pharmaceutical ingredients (API) which was subject to contamination, and a layer of dust and powder throughout the prescription counter and floors" that were "so dirty . . . an Investigator was able to write the initials 'DOH' with an alcohol swab on the pharmacy floor." Id. at 3. The DOH also found multiple expired medications and mislabeled syringes filled with medications that Mangini had compounded himself. Id. at 3-6. In addition, Mangini maintained poor recordkeeping and distributed prescription drugs, including at a local racetrack. Id. at 7-8. The DOH report set forth precisely why it mattered that Mangini maintain hygienic (lawful) practices: "Without the safeguards of sanitary conditions, audit trails and strict adherence to [requisite] standards . . . the public is at risk of the serious dangers, including death, associated with products originating from unsafe and unsanitary pharmacies. . . . A patient is unable to discern whether the medication he receives from a pharmacy is safe or dangerous, especially because the primary danger of contamination occurs at the microscopic level. It is therefore essential for pharmacists that prepare and sell medications to ensure that their practices and procedures are in strict conformity to the standards that have been set forth to minimize the inherent risk to the public and ensure the safety of the patients receiving medication." *Id.* at 8-9.

The DOH further concluded that Mangini was "incapable of performing the duties of a registered pharmacist . . . competently" based on "the number of significant and dangerous violations he committed in all aspects of practicing as the PDM at Ergogenic Labs." *Id* at 9. Notably, the DOH specifically cited Mangini's willful defiance of applicable regulations, stating that Mangini was "either unaware of, or disregards, his obligations" and "the laws and rules of the Board of Pharmacy and State of Florida regarding the practice of pharmacy." *Id.* at 9-10. After receiving this report and agreeing to restrictions on his license, Mangini did not seek to reform. Instead, with little interruption, he transplanted his operations to a new location, transferred certain staff, hired new staff, and continued supplying others with adulterated and misbranded drugs (in many cases, with the exact same adulterated and misbranded drugs he had sold previously). In other words, Mangini was undeterred.

This is evident from Mangini's conduct following the DOH inspection, in which he and his co-conspirators continued to dismiss concerns and evade scrutiny. For example, in an email dated April 5, 2017, the email account used by Racehorsemeds employees received an email from a buyer and re-distributor, passing along concerns from an industry professional, writing, "A horse website we're advertising on wrote this... The medical editor noticed you had acepromazine injection and a number of other injectables. Those were the ones he was questioning about needing a prescription." *See* Exhibit 13. An individual using the RHM Account responded later that day: "The best thing to do is to ignore any questions involving prescriptions and also any interviews and/or bad press, like The Paulick Report. They just seem to fizzle and go away." *Id*.

Third, a Guidelines sentence is just punishment for the offense because Mangini's practices actually resulted in harm to the receiving animals. As a general matter, the distribution of unregulated, untested drugs—including injectable and prescription drugs—to laypeople on the mass market carries with it serious consequences to the receiving animal. Any licensed pharmacist would surely be aware of these risks: Mangini, in particular, was directly notified that his practices

were deficient. Nonetheless, Mangini, motivated by greed, was callously indifferent to the medical risks he inflicted on the animals receiving his drugs by distributing misbranded and adulterated drugs, even when warned by his co-conspirator. Robinson told Mangini about adverse effects of his products on horses numerous times. In text messages sent on or about April 13, 2015 from Robinson to Mangini, Robinson wrote, "We have a problem with poly p / Horses infected and blowing after shot." Exhibit 6G.

Further, between December 2015 and January 2016—and during the period when Mangini and Robinson were partnered—a series of customers complained about a particular product distributed by Mangini, Robinson, and others, stating, among other things, that a mare who had been injected with Pentosan by a first-time user of this product "did not want to move at all and could not raise her head"¹¹; another individual stated that after two horses received the injection, "for about 36 hours . . . both my horses act like they are heavily sedated, can barely walk," and the user administered the product "three times"¹²; a third user reported that after injecting the horse with Pentosan, the horse experienced a stiff neck, which a veterinarian later identified as possibly caused by "some impurity in the batch."¹³ See Exhibit 6H. Mangini, rather than expressing concern, was instead totally dismissive, seeking to shift blame and responsibility. See id. ("ur not turning ur inventory as fast- so bottles sitting longer which make them more susceptible- only thing I can think of But these people also to blame too"); see Exhibit 6I ("These Momo's have no clue on injecting").

It is apparent that throughout the conspiracy, Mangini never took seriously the risks of his unsanitary practices to the receiving animals, and refuses to acknowledge these risks even today.

Finally, a substantial sentence is necessary to afford adequate specific and general deterrence. See 18 U.S.C. § 3553(a)(2)(B). With respect to specific deterrence, Mangini has engaged in the same type of conduct, illegally distributing adulterated and misbranded drugs, for almost a decade, which was only interrupted by the defendant's arrest. Even at a juncture point when Mangini faced irrefutable notice that his practices were unsanitary and illegal from the Florida Department of Health – and that he consequently risked losing his license – Mangini near-seamlessly continued his unlawful scheme from a new location unknown to state inspectors, albeit with changes designed to better hide Mangini's participation.

Given the proliferation of websites such as those operated by Mangini and his coconspirators, a significant sentence is warranted for purposes of general deterrence as well. Mangini, his co-conspirators, and others involved in the same activities have enabled the hazardous and illegal administration of unnecessary medications to performance animals with the goal of enriching themselves, and under the assumption that no serious consequences will follow if they

¹¹ The message relaying this complaint was sent from Robinson to Mangini on or about December 22, 2015.

¹² The message relaying this complaint was sent from Robinson to Mangini on or about January 2, 2016.

¹³ The message relaying this complaint was sent from Robinson to Mangini on or about January 4, 2016.

are ever caught. Imposing a substantial sentence here would send a strong signal to others thinking of engaging in such criminality that there will be consequences for their crimes.

Conclusion

The Government respectfully submits that a Guidelines sentence of 60 months is sufficient, but not greater than necessary, to serve the legitimate purposes of sentencing set forth in Title 18, United States Code, Section 3553(a).

Respectfully submitted,

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